Intensive Care Med (2005) 31:271
DOI 10.1007/s00134-004-2497-9

Ernst A. Singer
Christiane Druml

Collateral damage or *apocalypse now* for European academic research

Received: 8 October 2004
Accepted: 21 October 2004
Published online: 20 January 2005

The bureaucratic burden for academic investigators in Europe has tremendously increased since the implementation of the European Directive 2001/20/EC [1, 2, 3, 4, 5]. This increase neither contributes to patient protection nor to the scientific value of clinical trials. Furthermore, a number of new procedures have been added to the bureaucratic workload necessary before initiating a clinical trial. In this light, the request of the International Committee of Medical Editors (ICMJE) for a publicly accessible registry [6, 7, 8]—although a convincing strategy which adds transparency—also means a further increase in the bureaucratic paperwork for the investigators. The ICMJE member journals state that all trials starting enrolment after 1 July 2005 have to be previously registered in a database, otherwise these journals will refuse to publish the results. The goal of such an initiative is the prevention of undisclosed trials as well as duplicate and selective reporting.

While the merits of transparency of clinical research from the ethical point of view are not to be disputed [4], the argument that such a database creates "unnecessary bureaucratic delays and destroys the competitive edge" [6] of investigators should be taken more seriously than stated, as it mainly affects the academic researcher. One should also be alert to the fact that, in practice, a monopoly is created, namely the unavoidable use of the US-based registry www.clinicaltrials.gov. Even if this registry is currently available at no charge, who knows what the future brings if the demand is increasing and the maintenance workload, too. Although the BMJ has argued in an Editorial [5] that the choice of registry should not be too prescriptive, especially as the requested database only offers registration for specific types of research, it will also require registration of clinical trials before considering manuscripts for publication. We are strongly aware that such a requirement would again add more bureaucratic burden for the academic investigator, especially as the target group for such a registry is the pharmaceutical industry with big clinical trials.

We carried out a survey of projects submitted in 1998 to the Ethics Committee of the Medical University of Vienna: it appeared that of a total of 454 submitted protocols, the 23 studies which were published in the most renowned journals with the highest impact factor were academically sponsored trials. Interestingly, they involved a total of only 676 patients, that is, a mean of 29 patients per study. Such studies are exactly those that are hardest hit by bureaucratic requirements. However, this does not present the only problem: a most sensitive issue for the academic investigator is the requirement for a standardized pharmacovigilance. The standardized international terminology that is required by the European Directive is clearly the MedDRA terminology (e.g. Guidance document ENTR/CT13, 6.3.1.6.3). This is the only one available. When opening the respective website, the investigator quickly learns that "You can gain access to the MedDRA terminology by purchasing an annual, renewable subscription." Prices are referred to in US Dollars. On further inquiry he/she learns that purchasing the system is not enough: he/she has also to take courses in order to use it. These courses are held mostly in the United States.

While these facts alone constitute a substantial obstacle for an academic investigator to his/her research, he/she may also be disgusted by learning about the origin of the home of the database. A mouse click takes him/her directly to a wide selection of high-tech war material; for instance, he/she is instructed about the newest deals in centric warfare, covering submarines, aircraft carriers and long-distance missiles for conventional and nuclear weapons. Nothing is hidden as the website for the database is the official Northrop Grumman website (www.northropgrumman.com).

In 1998, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which was established as the Trustee of the International Conference on Harmonisation (ICH) Steering Committee for the purpose of holding the intellectual property rights of the terminology, selected Northrop Grumman Mission Systems (formerly TRW Inc., the Pentagon's prime contractor for intercontinental ballistic missiles) as the Maintenance and Support Service Organisation. Their activities are overseen by a management board, composed of the six ICH parties, the Medicines and Healthcare products Regulatory Agency of the UK, Health Canada, the World Health Organisation, and is chaired by the IFPMA.

Obviously, we have to accept the fact that Europe is supporting the monopoly of a US-based company which is mainly involved in supplying weapons to the Pentagon. This already odd situation is particularly irritating as issues of clinical research are concerned, which must always be conducted under the strictest adherence to ethical guidelines. Everyone who has ever dealt as a researcher with US authorities or participated in a US clinical research project knows how non-US institutions are scrupulously scrutinized for their human subjects protection programs. Shouldn't Europeans consider steps to protect their academic researchers from exposure to such dubious double standards?

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E. A. Singer · C. Druml (✉)
Ethics Committee
of the Medical University of Vienna,
Borschkegasse 8b,
1090 Vienna, Austria
e-mail: christiane.druml@meduniwien.ac.at